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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,262	01/05/2000	NIKOLAUS THERES	11216/002001	7039

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EXAMINER

MEHTA, ASHWIN D

ART UNIT PAPER NUMBER

1638

DATE MAILED: 03/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/403,262

Applicant(s)

THERES, NIKOLAUS

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23,25-36 and 38-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23,25-36 and 38-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objections to claims 27-29, 31, 32, 40, and 41 are withdrawn, in light of the claim amendments or further consideration.

Claim Rejections - 35 USC § 112

3. Claims 23, 25-36, and 38-42 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons for record stated in the Office action mailed September 12, 2003. Applicant traverses the rejections in the paper filed January 12, 2004. Applicant's arguments have been fully considered but were not found fully persuasive.

Regarding the recitation, "highly stringent conditions" in claim 23: Applicant again argues that page 29 of the specification states that reduced stringency includes up to 55°C, and that anything higher would be high stringency (response, page 5, last paragraph). However, the specification makes no such indication. It is not at all clear that 56°C, for example, would be part of a moderate stringency condition, and not a high stringency condition. Applicant also argues that one can determine other parameters of wash conditions, other than temperature (response, page 5, last paragraph). However, it is not clear how one can determine that a particular condition is considered to be highly stringent in the context of the instant application.

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The specification does not provide conditions for any washes of hybridizations. Further, what is considered to be highly stringent to one may not be considered highly stringent by another.

Applicant also argues that the term was well known and conditions that satisfy this term were known in the art. Applicant also argues that page 23 sets forth salt conditions for hybridization, and in combination with the temperatures for hybridization on page 9 and temperatures for reduced stringency on pages 17 and 29, that it would be clear to the skilled artisan that conditions for stringent hybridization are the salt conditions on page 23 and temperatures above 55°C (response, page 6, 2nd full paragraph). However, the specification does not define that all conditions in which the temperature is above 55°C is defined as highly stringent.

Regarding the term “derivative” in claim 23: Applicant indicates that the claims have been amended to remove this term (response, page 6, 3rd full paragraph). However, line 9 of claim 23 still recites “said fragment or derivative.” As all previous recitations of “derivative” were removed by the amendment, there is now insufficient antecedent basis for the remaining recitation.

Applicant did not respond to the following indefinite issue concerning claim 23 raised in the last Office action: it is not clear if the isolated nucleic acid comprises both the nucleic acid of (a) and the fragment or derivative of (b). If it comprises both, it is suggested that the conjunction, --and--, be inserted in line 5 after “formation;”. If it comprises only one of the two, it is suggested that --or-- be inserted in line 5 after “formation;”.

Regarding claims 25 and 26: upon further consideration the rejection of these claims, for not clearly indicating if the fragment or derivative of claim 23 is still encompassed, is withdrawn.

Regarding claims 35 and 36: Applicant argues that the claims have been amended (response, 7, 1st full paragraph). The amendment overcomes the rejection for claim 35. However, claim 36 does not indicate whether the nucleic acid molecule is in sense or antisense orientation. Antisense sense sequences can potentially still be translated. It is suggested that the following recitation be inserted at the end of the claim, --into said polypeptide--.

4. Claims 23, 25, 27-36, and 38-42 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed September 12, 2003. Applicant traverses the rejection in the paper filed January 12, 2004. Applicant's arguments have been fully considered but were not found persuasive. The rejection is withdrawn from claim 26, as that claim limits the nucleic acid of the isolated nucleic acid molecule of claim 1 to comprise the nucleotide sequence of SEQ ID NO: 1.

Applicant indicates that the claims were amended to remove the term, "derivative" (response, page 8, 2nd full paragraph). However, the claims still read on fragments of SEQ ID NO: 1 that encode polypeptides having the biological activities of shoot formation, petal formation, and abscission zone formation, which are not described in the specification. Applicants argue that examples are not required, and again argue that one skilled in the art would not doubt, given the disclosure, that derivatives satisfying the claim limitations could be created (paragraph bridging pages 7-8). Applicants argue that the present issue is not analogous to the

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issue in Fiers v. Sugarno, in that here the claims refer to the nucleotide sequence of SEQ ID NO: 1, and then extend a functional umbrella around this sequence based upon the ability of a nucleic acid to hybridize to SEQ ID NO: 1 and to encode a polypeptide having the aforementioned activities (response, page 8, 1st full paragraph). However, SEQ ID NO: 1 does not encode just a portion of polypeptide, but rather a complete polypeptide. There is not a single species of fragments of SEQ ID NO: 1 described in the specification that encodes a polypeptide that retains the activity of SEQ ID NO: 2. Applicants argue that an example is not required, and that one would know how to create all of the nucleic acids encompassed by the claims based on the teachings of the specification. However, the specification does not describe the sequences of SEQ ID NO: 2 that are essential to its functional activity. The specification does not indicate what sequences of SEQ ID NO: 1 are shared among the genus of fragments, and does not correlate the structure of any fragment of SEQ ID NO: 1 with the functional activity of SEQ ID NO: 2. The specification does not present any evidence that any fragment of SEQ ID NO: 2 retained the biological activities of being involved in shoot formation, petal formation, and abscission zone formation.

As discussed above, Applicant has indicated that the claims were amended with the intention to no longer encompass derivatives.

5. Claims 23, 25-36, and 38-42 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

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claimed invention for the reasons of record stated in the Office action mailed September 12, 2003. Applicant traverses the rejections in the paper filed January 12, 2004. Applicant's arguments have been fully considered but were not found persuasive.

Applicant argues that the term is well known to those of skill in the art, and that highly stringent conditions are differentiated from "reduced stringency", as mentioned *per se* in the application (response, paragraph bridging pages 8-9). However, whether or not a term is known in the art is irrelevant. The recitation of "reduced stringency" also does not provide written descriptive support for other recitations.

Further, as discussed above, Applicant has amended claim 23 with the intention to remove derivatives from the claim scope. The relevance of reciting hybridization conditions is therefore no longer clear. It is suggested that that last two lines of claim 23 be deleted.

6. Claims 23, 25-36, and 38-42 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the Office action mailed September 12, 2003. Applicant traverses the rejection in the paper filed January 12, 2004. Applicant's arguments have been fully considered but were not found persuasive.

Regarding the issue of the phenotype of transgenic plants overexpressing SEQ ID NO: 1 Applicant provides another declaration signed by the inventor, in which the inventor addresses a statement made in the previously submitted declaration. The statement concerns the result of an

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experiment in which an ls mutant tomato plant was transformed with the tomato Ls gene. The first declaration indicated that the transgenic plant showed increased shoot formation, and the recently submitted declaration clarifies that statement by indicating that the increase in shoot formation was in comparison to not only the non-transformed mutant plant, but also to a wild-type plant (response, paragraph bridging pages 9-10; declaration, item 7). However, it remains that this conclusion is based on data collected from transformation of a mutant plant. Further, in that particular experiment, the declaration teaches that the transgenic plant developed an incomplete whorl of petals on its flowers, indicating only a partial complementation (declaration submitted May 12, 2003, item 9). It is also noted, as discussed in previous Office actions, that the specification indicates that wild type plants were transformed with the tomato Ls gene in sense orientation. It is again suggested that Applicants submit the phenotype of these plants in a declaration.

Applicant presents arguments as to why derivatives of SEQ ID NO: 1 are enabled (response, pages 10 and 11). However, as discussed above, Applicants have indicated in their response that the claims were amended to remove the term, "derivatives." While one such recitation of the term remains in claim 23 (the presence of which renders the claim indefinite, as discussed above), Applicant's arguments to the other rejections have indicated that the amended claims were not intended to encompass derivatives. It is therefore unclear why Applicant is arguing for their enablement here. Applicant's arguments will be addressed as they pertain to fragments of SEQ ID NO: 1, as fragments are still encompassed by the claims.

Applicants argue that one of skill in the art is more than capable of making small deletions, each of which retain the ability to promote shoot, abscission zone, and side-shoot

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formation, and that the Examiner supposedly acknowledged as much (response, page 10, 1st full paragraph). However, the Examiner did not make this acknowledgement. The Examiner only acknowledged that one skilled in the art is capable of making fragments of nucleotide sequences. No acknowledgement was made as to the enablement of making fragments with the express knowledge of the functional activities of those fragments. Further, the claims do not state that only small deletions of SEQ ID NO: 1 are encompassed by “fragments.”

Applicant argues that it is black letter law that it is not the function of claims to exclude possible inoperative substances. Applicant also states that such inoperative species are specifically excluded from the claims (response, page 10, 2nd full paragraph). However, there are no fragments that are enabled by the specification at all. While a claim may encompass non-enabled embodiments, not a single operative fragment is enabled by the specification. The specification does not teach a single fragment of SEQ ID NO: 1 that encodes a polypeptide that promotes shoot, abscission zone, and side-shoot formation.

Applicant also again points to the declaration from Dr. Theres, which present the results of an RNAi experiment in which some of the recovered transgenic plants showed a reduction in petal and side-shoot formation. Applicant argues that the results demonstrate that Ls sequences can be used to suppress side-shoot, petal, and abscission zone formation, and that although a full-length coding sequence was used, the experiment argues in favor of the utility of fragments of the Ls gene (response, page 11). However, the prior Office actions did not raise the issue of the enablement of the claimed method to suppress side-shoot, petal, and abscission zone formation in plants. Further, the experiment does not address the issue of fragments of SEQ ID NO: 1 that

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encode polypeptides that have the biological activity of promoting side-shoot, petal, and abscission zone formation.

Summary

6. Claims 23, 25-36, and 38-42 remain rejected.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

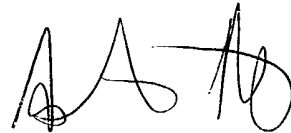
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ashwin Mehta whose telephone number is 571-272-0803. The examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached

at 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 24, 2004

A handwritten signature in black ink, appearing to read 'Ashwin D. Mehta', with a stylized flourish at the end.

Ashwin D. Mehta, Ph.D.
Primary Examiner
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